

REMARKS

Applicants gratefully acknowledge the telephone interview conducted between the Examiner, Dorothy R. Auth, and the undersigned.

Claims 1-35 have been cancelled. Claims 36-37, 55, 56, 58, 59, 62, and 68 are currently amended. Claim 75 is new. Support for the amendments made to the claims are provided throughout the specification and claims. Changes made in this amendment are merely to clarify the claims. No new matter or new issues of patentability are introduced by this amendment.

CLAIM OBJECTIONS

6. Claim 56 has been objected to for reciting the phrase "obtaining preserved a cell." Please amend the claim to recite the phrase "obtaining a preserved cell" as suggested by the Examiner. Applicants respectfully request reconsideration and withdrawal of this objection.

DRAWINGS

Applicants enclose herewith formal drawings, and associated papers, as to be submitted to the Official Draftsperson.

CLAIM REJECTIONS

7. Claims 36-48, 51-54, 58, 59, and 61 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy, et al. Applicants respectfully disagree with the Examiner's assertion that the claimed invention is obvious over Dunphy. The Dunphy reference discloses a medium for fixing tissue for histological procedures. In view of the previously submitted Declaration under 37 C.F.R. §1.132, applicants show that Dunphy's Example 4 formulation is not capable of adequately preserving DNA and RNA for molecular analysis. In addition, applicants have amended independent claims 36, 37, 58, and 59 such that the claims are directed to a collection medium that is sufficiently stable to allow morphological analysis and quantitation of RNA, DNA or proteins in a cellular sample. Dunphy does not teach or suggest a medium which is sufficiently stable to carry out both morphological and quantitative analyses. Dunphy does not even attempt to do this because the focus of the Dunphy reference relates only to tissue analysis. Dunphy does not teach or suggest a medium

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capable of both morphological and quantitative analyses, as claimed. Therefore, applicants respectfully request reconsideration and withdrawal of this 35 U.S.C. §103(a) rejection.

8. Claims 49, 55-57, 60, and 68-74 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy, et al. as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Weber in view of Harrison. The Examiner contends that Dunphy as applied to Weber and Harrison makes it obvious to use tissue samples treated with the collection medium of Dunphy for methods of DNA and protein analysis, as Weber shows that such media can be used for DNA hybridization studies and Harrison shows that such media may be used for antigen analysis. Applicants respectfully disagree with this rejection.

As stated above, Dunphy's Example 4 formulation does not adequately preserve nucleic acids for direct molecular analysis. Neither Weber nor Harrison remedies this defect. There is no teaching or suggestion within Weber to instruct one skilled in the art to modify this medium in relation to Dunphy's Example 4 formulation such that the combination would result in a formulation that allows the direct molecular analysis of nucleic acids and proteins. Further, there is no reasonable expectation that any such combination would succeed in forming a medium as claimed.

Harrison does not describe a collection medium. Harrison merely describes, a fixative which is pre-applied to a substantially dry, non-fluid surface, slide or other test surface to which the sample is applied (column 1, lines 41-45). Harrison describes a dry fixation process for antigen analysis. One skilled in the art could not reach the instant method claims based on the teachings of Dunphy in combination with Harrison. Further, Dunphy in combination with Harrison and Weber still do not guide one skilled in the art to a useful formulation as claimed, because neither Dunphy nor Harrison nor Weber provide a specific formulation capable of preventing degradation of nucleic acids and proteins. However, in order to expedite prosecution of the present application, applicants have amended independent claims 36, 37, 58, and 59 such that the claims are directed to a collection medium that is sufficiently stable to allow morphological analysis and quantitation of RNA, DNA or proteins in a cellular sample. Neither Dunphy, Harrison, or Weber taken alone or in combination teach or suggest a medium capable of analyzing both the morphology and quantitation of molecular components. Therefore, reconsideration and withdrawal of this 35 U.S.C. §103(a) rejection is respectfully requested.

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9. Claims 62-66 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy, et al. as applied to claims 36-48, 51-54, 58, 59, and 61, and further in view of Wainwright. The Examiner contends that Wainwright discloses an article of manufacture comprising a container, a lid fitting the container and a brush for preserving a cellular sample. Applicants respectfully disagree with this ground of rejection.

As discussed above, Dunphy fails to teach or suggest the claimed invention because it does not teach a cell preservation medium that is capable of sufficiently preserving nucleic acids and/or proteins for direct quantitative molecular analysis. Wainwright does not remedy the defect of Dunphy, but rather merely describes a container with a lid and a brush. Wainwright refers to a fixative only once (column 5, lines 43-44). Wainwright does not disclose what this cytofixative may be composed of, nor does Wainwright disclose that this cytofixative may enable the fixation of cells for molecular analysis. Therefore, the combination of Wainwright with Dunphy does not rectify the inability of Dunphy 's medium to adequately preserve nucleic acids for direct molecular analysis. However, in order to expedite prosecution of the present application, applicants have amended independent claims 36, 37, 58, and 59 such that the claims are directed to a collection medium that allows morphological analysis and quantitation of RNA, DNA or proteins in a cellular sample. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

10. Claim 67 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy, et al. as applied to claims 36-48, 51-54, 58, 59, and 61, and further in view of Wainwright, and further in view of Weber in view of Harrison.

As previously described, Wainwright, Weber and Harrison do not teach or suggest a remedy for the deficiencies in Dunphy's Example 4 formulation. There is no guidance in this combination of references to provide a successful medium composition capable of adequately preserving cells or tissues for the direct quantitative molecular analysis of nucleic acids and proteins. The combination of Weber and Harrison is improper because Weber discloses the use of proteolytic and denaturing agents (such as proteinase K and guanidine isothiocyanate) that would not enable the further analysis of proteins. As previously discussed, Harrison describes the use of a dry fixative process, and therefore provides no teaching or suggestion for a tissue preservation medium. Lastly, Wainwright makes no suggestion or teaching that its article of manufacture may be used to collect cells for protein or nucleic acid analysis;

rather Wainwright only directs one skilled in the art that the invention is useful for the cytologist in analyzing pap smears. Thus, applicants respectfully disagree with the combination of Dunphy, Wainwright, Weber and Harrison because the combination is improper and because the combination does not remedy the defects in the primary reference. However, in order to expedite prosecution of the present application, applicants have amended independent claims 36, 37, 58, and 59 such that the claims are directed to a collection medium that is sufficiently stable to allow morphological analysis and quantitation of RNA, DNA or proteins in a cellular sample. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

CONCLUSION

There being no other outstanding issues in this case, allowance of the pending claims is respectfully requested. Early and favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this amendment under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4005US1.

Respectfully submitted,
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